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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,392	11/23/2001	George Jackowski	2132.097	4945

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EXAMINER	
CHEU, CHANGHWA J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,392	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 39-46* is/are pending in the application.

4a) Of the above claim(s) *39-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 1/12/2005
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment filed on 6/5/2005 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 2-38 are cancelled.

2. Claims 1 is under examination.

3. For the request of rejoining claims 39-46 under In re Ochaia with claim 1, since the current claim 1 is still not allowable (see below), the rejoining would not be considered. Accordingly, claims 39-46 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

> As set forth in *In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)*, enablement requires that the specification teach those skilled in the art to make and use the invention without undue experimentation. Factors to be considered in determining, whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the

quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

The instant invention directs to a method of diagnosing insulin resistance patients using particular biomarkers, such as residues 2-11 of SEQ ID No. 1, residues 2-12 of SEQ ID No. 2 and residues 2-13 of residues of SEQ ID No. 3 as recited in claim 1.

The instant invention is characterized by the use combination of preparatory steps, e.g. chromatography and I-D tripcine polyacrylamide gel electrophoresis. Subsequent to which the gel is stained, e.g.' with Coomasie blue, silver or rubidium. Next, bands are selected from the gels for further study. Tryptic digestion of each band follows, concluding with the extraction of tryptic peptides from the digest. This extraction may be accomplished utilizing C18 ZIPTIPS, or organic extract and dry technique followed by MALDI Qq TOF (Maldi Quadrupole Quadrupole Time of Flight) processing. Additional methodologies may include SELDI MS, gel technology, MALDI MS/MS and time-of-flight detection procedures to maximize the diversity of biopolymers which are verifiable within a particular sample. The cohort of biopolymers verified within a sample develop data indicating their presence, then compared to absence or relative strength/concentration in disease vs normal controls, and further studied to determine whether the up-regulation or down-regulation single biopolymer or group biopolymers is indicative of a disease state or predictive of the development of said disease state (See page 25, last paragraph to the second paragraph of page 26).

The data shows that there is a "up regulation" (appearing a band #9 on the PAGE gel on the insulin patients but not in other normal people). The band 9 is approximately less than 3 KD through proteolytic digestion (See page 38, second paragraph). Through the previous described steps applicant identify certain fragment, such as SEQ ID No. 1, 2 and 3 as the unique biomarkers specific for insulin resistance patients.

In view of the data, the instant invention still suffers insufficiency which would not be enable one ordinary skill in the art to use this invention without undue experimentation. The identified SEQ ID No. markers are for diagnosis purpose. Applicant indicates that mass spectrum profile of the digested peptides, i.e. SEQ ID No. 1-3 with their respective residues, is an indication of the insulin resistance disease (See page 39, first paragraph to page 40, second paragraph). However, in view of the mass spectrum of the peptides as in Figure 2 and 4, there is not explanation or illustration what is the significance or relationship between these peptide fragments and the insulin resistance. Figure 2 is merely a trysin digested spectrum graph depicting ion 1208, whereas Figure 4 is a trypsin digested spectrum graph depicting ion 1447. There is no indication which graph represents insulin resistance patients. There is no indication where are the SEQ ID No. fragments or the corresponding relationship to the insulin resistance. Ultimately, there lacks a scientific *nexus* between the mass spectrum of the recited SEQ ID No. 1-3 and the target disease (emphasis added).

In view of the guidance of In re Wands, 8 USPQZd 1400, it has been determined that the level of experimentation required to enable the breadth of the claims is undue. Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966). While every aspect of a generic claim does not have to be carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. Genetech Inc. v. Novo Nordisk A/S ICAFCI 42 USPQ 2d 1001. That requirement has not been met in this specification with respect to the biopolymer consisting of SEQ ID NO 1-3 for diagnostic for Insulin Resistance. Therefore, in view of the insufficient guidance in the specification, extensive experimentation would be required to enable the claims and to practice the invention as claimed.

Response to Applicant's Applicant

Enablement

The enablement rejection under 35 USC 112, first paragraph set forth in the previous Office is withdrawn. In view of applicant's Remarks and Declaration (9/16/2003), examiner considers 2 insulin resistance patients with 6 compared people satisfying *In re Wands* requirements, i.e. sample size. However, claim 1 is still rejected under enablement (a new issue) set forth in this Office Action.

Prior art rejection

3. Both the rejections under 35 USC 102(b) of Borden et al. (WO 96/04790) and Waterham et al. (Biochem Biophy Res Comm 1999 Vol. 263, page 213) are withdrawn.

Conclusion

4. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641

June 9, 2005

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

05/10/05